December 13, 2017

Hon. Claire C. Cecchi, U.S.D.J.
United States District Court for the District of New Jersey
Martin Luther King, Jr. Bldg. & U.S. Courthouse
Courtroom MLK 5B
50 Walnut Street
Newark, NJ 07101

Re: Proton-Pump Inhibitor Products Liability Litigation (No. II); 2:17-md-2789 (CCC)(MF) (MDL 2789)
Defendants' Proposal Regarding the Plaintiff Fact Sheet

Gregory J. Hindy
Partner
T. 973-639-6954
F. 973-297-3883
ghindy@mccarter.com

McCarter & English, LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102-4056
T. 973.622.4444
F. 973.624.7070
www.mccarter.com

BOSTON
HARTFORD
STAMFORD
NEW YORK
NEWARK
EAST BRUNSWICK
PHILADELPHIA
WILMINGTON
WASHINGTON, DC

Dear Judge Cecchi:

Pursuant to this Court's Order on the record on November 8, 2017, we write on behalf of all Defendants, seeking entry of a Plaintiff Fact Sheet ("PFS") in the form proposed by Defendants, a copy of which is attached as **Exhibit A**.

I. Introduction

Defendants' proposed PFS is drafted narrowly to obtain relevant and discoverable information about each individual plaintiff's medical history, pertinent personal information, PPI use, alleged injuries, and claims. As the Court is aware, PPIs, made by multiple defendant manufacturers, have been on the market for decades and are alleged by the coordinated plaintiffs to have caused a myriad of kidney-related issues. Because of these complexities and because, generally speaking, the PFS will be Defendants' sole means of obtaining written discovery and documents relevant to many of the individual plaintiffs' claims against the various defendants, the PFS is necessarily expansive and comprehensive. That said, every inquiry relates to the issues raised by Plaintiffs' claims and is designed to enable Defendants to assess the allegations against them and prepare their respective defenses. *See, e.g., In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 460 F.3d 1217, 1234 (9th Cir. 2006) (explaining that "the purpose of the Plaintiff's Fact Sheet was to give each defendant the specific information necessary to defend the case against it, and that without this device, defendant was unable to mount its defense because it had no information about the plaintiff or plaintiff's injuries outside the allegations of the complaint").

Despite the obvious necessity of a comprehensive PFS, Plaintiffs seek to delete and/or alter numerous inquiries with no substantive rationale. The significant and overarching areas of dispute which are addressed herein include the following:

- The proportionality between the discovery Plaintiffs seek in this litigation and the constraints they seek to impose on Defendants;
- Plaintiffs' insistence that the scope of inquiry in the PFS be limited to five or fewer years;
- Plaintiffs' refusal to allow any inquiry regarding the plaintiff's family history of kidney disease or conditions;
- Plaintiffs' refusal to allow any inquiry into the plaintiffs' social media presence and relevant on-line activity; and
- Plaintiffs refusal to provide blank authorizations to allow Defendants to obtain records from the plaintiff's providers without having repeatedly to request pre-addressed authorizations to specific providers from the plaintiff's counsel.

Additionally, these issues, as well as other individual items, are separately addressed in **Exhibit B**, an annotated version of Plaintiffs' redlined draft setting forth Defendants' responses to each redlined edit.

II. Status of the PFS Negotiations

On November 20, 2017, Defendants sent a draft PFS to counsel for Plaintiffs.[1] On December 5, 2017, counsel for Plaintiffs sent Defendants a redlined draft of the PFS. Plaintiffs struck certain inquiries and provisions, largely without explanation, made a handful of vague comments, and offered other minor revisions. On December 12, 2017, the parties met and conferred regarding Plaintiffs' proposed redline edits to the draft PFS. That same day, Defendants sent Plaintiffs a further redline draft, accepting certain of Plaintiffs' proposed revisions and rejecting others. The draft PFS attached as Exhibit A incorporates those revisions Defendants accepted.

III. Argument

In accordance with Federal Rule of Civil Procedure 26, "'[p]arties may obtain discovery regarding any non-privileged matter that is relevant to any party's claim or

[1] The draft PFS Defendants sent to Plaintiffs on November 20th was based on the draft that was being negotiated between the parties in the District of New Jersey PPI litigation prior to the formation of the MDL. To the extent that Defendants made compromises or concessions in connection with the earlier draft PFS, those compromises and concessions are reflected in the draft that was sent to Plaintiffs on November 20th.

defense . . . . Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence.'" *Okereke v. Allen*, No. 15-7083 (PGS), 2017 WL 2450282, at *1 (D.N.J. June 6, 2017) (quoting FED. R. CIV. P. 26(b)(1)); *see also Mondis Tech. Ltd. v. LG Elecs., Inc.*, No. 15-CV-4431(SRC) (CLW), 2017 WL 4155121, at *2 (D.N.J. Sept. 19, 2017) ("Under Rule 26, 'parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case.'")

A. Discovery Procedures and Obligations between the Parties Should Be Proportional

1. Plaintiffs have sought discovery from Defendants spanning 50 years and involving millions of pages of documents.

To date, Plaintiffs have sought voluminous discovery from Defendants consisting of hundreds of interrogatories, hundreds of individual document requests, demands for information relating to and/or testimony from hundreds of witnesses, and the production of millions of pages of documents. They have already served numerous Rule 30(b)(6) notices on the various defendants covering a host of topics; taken a number of corporate representative depositions (and now demand that additional corporate representatives be produced to testify with respect to matters and information prior to 1999); served requests for production consisting of sets of more than 60 individual requests; demanded that defendants identify and produce for deposition multiple records custodians; and demanded that individual defendants identify and produce documents from multiple databases. Moreover, they seek to sweep into this discovery documents and witnesses going back more than 50 years (even though the inaugural PPI product was first sold in the United States less than 30 years ago) and demand that this discovery for the most part be completed in a few months' time.

For example, Plaintiffs' broad reaching discovery requests, as to Defendant AstraZeneca alone, include – over the span of a 52-year period -- all drafts of promotional materials that were never used or disseminated outside the company, laboratory notebooks for thousands of individual studies of the products, the underlying contracts with all individual investigators who ever performed any studies on the products, including animal studies, notes from every phone conversation between AstraZeneca employees regarding the development or testing of the products, all documents, emails, or memos relating to any consideration of any labeling change for the products, whether related to Plaintiffs' claimed injuries or not, all notes or records concerning any interactions by any AstraZeneca employees

with prescribers of the products, whether related to Plaintiffs' claimed injuries or not, and many other categories.

Against that backdrop, Plaintiffs attempt to limit Defendants' ability to obtain basic – relevant and discoverable -- information from individual plaintiffs via the PFS process. They have objected entirely to inquiries into the plaintiff's relevant family medical history, prescription medication use, social media presence and relevant activity, and other discoverable matters. Moreover, despite the existence of many plaintiffs who claim in their complaints to have taken PPIs for many years, Plaintiffs seek to limit the scope of the PFS to five years (and, in some specific instances, to two or three years).

More than a year into this litigation and five months into this MDL, Plaintiffs have yet to agree to the substance of the PFS or a procedure by which individual plaintiffs will produce any information or documents, let alone core material relating to their PPI use or a kidney-related injury. Defendants have been unable to learn anything about the claims against them other than what is alleged in the complaints. For the vast majority of the plaintiffs, the PFS constitutes the only written discovery request to which they will be required to respond. Thus, the PFS should include information to allow Defendants not simply to determine which PPI, if any, the plaintiff took and whether he or she suffered a qualifying injury (although such information is critical), but to allow Defendants to mount their defenses. Moreover, as the PFS will apply to *all* plaintiffs in this MDL, it must contemplate Plaintiffs' broad range of current and potential allegations. Every inquiry in Defendants' proposed PFS is calculated to achieve that end.

In Plaintiffs' markup of the draft PFS, however, not only have Plaintiffs deleted inquiry after inquiry for no stated reason other than that they simply do not think they are "necessary," they have sought to limit nearly every category of information, including prior primary care physicians/healthcare providers and past employment history, to a temporal scope of only five (5) years. They have also limited the inquiry concerning a plaintiff's total earned income from Defendants' proposed ten (10) years to only three (3) years. On its face, Plaintiffs' limitations are unreasonable, particularly given that some plaintiffs do (and other future plaintiffs may) allege PPI use and/or injury dating back significantly more than 5 or even 10 years ago.

The targeted PFS proposed by Defendants pales in comparison to the broad, sweeping discovery Plaintiffs have sought and are seeking from Defendants. Defendants' PFS already is the result of significant compromise as to discovery to which Defendants would otherwise be entitled from the various plaintiffs in this

MDL. Defendants therefore suggest that the Court approve Defendants' proposed PFS as written and reject all of Plaintiffs' proposed revisions. Plaintiffs' broad stroke reduction of the scope of the requests in Defendants' proposed PFS; their wholesale deletion of relevant areas of inquiry; and their effort to hamper Defendants' ability to obtain records from Plaintiffs' providers are inconsistent with permissible discovery precepts under the Federal Rules and with plaintiff fact sheets and corresponding procedures adopted by numerous MDL courts in similar past pharmaceutical litigation.

2. Plaintiffs improperly seek to limit the scope of the PFS.

In their proposed PFS, Defendants limit to a period of 15 years their inquiries into core issues like the plaintiff's medical history, healthcare providers, medication use, and the like. The 15-year period itself represents a compromise from the time period of potentially discoverable information – particularly given that some plaintiffs have already alleged use of PPI products well beyond 15 years ago. Likewise, the plaintiff population is not disproportionately young; therefore, it certainly is conceivable (if not undisputed) that a plaintiff's pertinent medical history (which may include other risk factors or alternative causation factors) would include information and discovery more than 15 years in the past. Plaintiffs cannot dispute that they are suing Defendants over the use of products they took, in some instances, 20 or more years ago, and some of those products have been on the market for 30 years.

When negotiating the PFS in the District of New Jersey PPI litigation, Defendants initially proposed a time period of 20 years for such inquiries. Plaintiffs refused and reduced it to 10 years.[2] While 20 (or more) years is a reasonable time frame, given the products and injuries at issue, and Plaintiffs' claims themselves, in the spirit of compromise, Defendants offered a time frame of 15 years. As noted above, when drafting the PFS in this MDL, Defendants honored those compromises they had agreed to in the District of New Jersey litigation and, thus, included in the draft before the Court a time frame of 15 years (or, in some instances, fewer).

In Plaintiffs' recent markup of the draft PFS, however, Plaintiffs limited nearly every category of information, including prior primary care physicians/healthcare providers and past employment history, to a temporal scope of only five years. Plaintiffs also reduced the inquiry concerning a plaintiff's total earned income from Defendants' proposed ten years to only three (3) years, and they add similar time constraints to a

[2] Remarkably, Plaintiffs even initially tried to limit inquiry into the plaintiff's use of PPIs to a period of ten years, while at the same time alleging that Plaintiffs long-term use of PPIs dating back well over ten years caused their injuries.

number of other relevant inquires.[3]

Those limitations impermissibly restrict the discovery to which Defendants would otherwise be entitled in a given plaintiff's individual case. In other words, because the PFS will be applicable to all MDL plaintiffs, the designated time periods must account for the wide array of potential fact patterns presented by this already heterogeneous group of plaintiffs, as well as those to come. Otherwise, Defendants' right to discovery (to which Defendants undeniably would be entitled in a particular individual plaintiff's case) would be abridged simply because the plaintiff's case is part of an MDL.

a. The complaints already part of this MDL demonstrate the need for at least a 15 year time period as proposed by Defendants.

A sampling of PPI complaints illustrates the unreasonableness of Plaintiffs' five-year limitation. For example:

- Plaintiff Betty All alleges she "first began using prescription brand Prilosec in or about September 2000 . . . until April 2002," and that she "first began using prescription brand Nexium in or about May 2002 . . . until April 2016." *All v. AstraZeneca Pharmaceuticals LP, et al.*, No. 2:17-cv-5972, Compl. at ¶¶ 13-14.

- Plaintiff Mike Allen alleges he began taking Nexium and Prevacid "as early as 1995, and consistently thereafter through 2012." *Allen v. AstraZeneca Pharmaceuticals, LP, et al.*, No. 2:17-cv-10485, Compl. at ¶ 81.

- Plaintiff Manuel Leon alleges he ingested Nexium "beginning as early as 1998, and thereafter through 2016." *Leon v. AstraZeneca Pharmaceuticals LP, et al.*, No. 2:17-cv-07955, Compl. at ¶ 67.

These allegations are typical of the complaints already before this Court and are likely to be found in cases that will subsequently be part of this MDL. If those cases were individual actions and not part of an MDL, discovery reaching back 20 or more years undeniably would be proper merely in light of the allegations in the complaint. Plaintiffs may argue that five years is reasonable because some individuals are young

[3] To the extent the court agrees with Plaintiffs and limits discovery on earned income to three years, fairness dictates that any damages claims for lost income should also be limited to three year unless and until additional information about earned income is produced for the entire claimed damages period.

and only used PPIs for a short time. True or not, the PFS is a tool used across all cases in the MDL. Plaintiffs cannot restrict Defendants' right to discovery using the least common denominator.

Further, Plaintiff's position is indefensible, considering the products and injuries at issue. This is not a case where the litigation involves a single product that has been on the market only a few years, potentially making a more abbreviated time frame reasonable. Indeed, for a plaintiff who started taking PPIs as far back as the mid-1990s, his or her medical history dating from the 1990s, the names of healthcare providers and facilities during the time he or she was taking PPIs, other medications he or she was taking while also taking PPIs, and where he or she lived and worked are all reasonable areas of inquiry.[4]

Splitting the proposed time periods (i.e., 10 years) in this instance is unacceptable, if for no other reason that allegations in currently-filed cases already demonstrate that information dating beyond 15 (or even more) years in the past is relevant to Plaintiffs' claims and Defendants' defenses. Moreover, as noted above, Defendants' proposed scope already represents a compromise from their earlier draft PFS.

b. Plaintiffs seek to limit Defendants' scope of inquiry to five years while at the same time seeking discovery from Defendants unlimited in time and virtually unlimited in scope.

Plaintiffs' five-year limitation position is even more unreasonable when contrasted with the scope of the discovery they seek from Defendants. For example, they have served interrogatories on Defendants unlimited in time. They have served document requests reaching back 30 or more years. And they have sought to depose Defendants' corporate representatives on matters dating back 30, and in some cases, 50, years. As to AstraZeneca alone, Plaintiffs have served a total of 167 document requests seeking, among other things, insurance information and quarterly reports for the past 28 years and internal documents and information relating in any way to PPI products for the past 52 years. They have served a total of over 100 interrogatories (including subparts) unlimited in scope and time. And they have demanded that

[4] Arguably, in a case like that of plaintiff Allen described above, limiting discovery to five years would almost certainly mean that Defendants would never be able to obtain information about healthcare providers, the plaintiff's medical history, medication history and the like during the many years he or she was using PPIs prior to five years from the date of the PFS, because it is likely that such information would not be included in the plaintiff's current and more recent medical and pharmacy records. Thus, a five-year time frame would result in an incomplete picture of the plaintiff and his or her claims.

AstraZeneca produce multiple corporate representatives to testify on a total of 150 topics spanning a 50-year period.

Defendants seek fifteen years' worth of pertinent personal, medical, and product use information from each person demanding that Defendants be required to award him or her damages. This is an objectively reasonable position and is even more reasonable when weighed against the broad, and in many instances objectionable, discovery Plaintiffs are seeking from Defendants.

B. A Plaintiff's Family History of Kidney Disease is Relevant and Discoverable

Defendants' proposed PFS contains a single inquiry regarding the plaintiff's family history of kidney disorders:

> Has any child, parent, sibling, or grandparent of yours related to you by blood ever been diagnosed with any of the injuries or conditions identified in your answer to question IV.A.2., above, including but not limited to, acute kidney injury, acute interstitial nephritis, chronic kidney disease, kidney failure, end-stage renal disease, renal transplant, dialysis treatment, etc.?

See PFS at 28-29. It is well established that the kidney disorders alleged here have significant genetic components and causes. *See, e.g.*, https://emedicine.medscape.com/article/243597-overview#a5, at p. 3 (genetics is one cause of interstitial nephritis). Bleyer AJ, et al., Hereditary Interstitial Kidney Disease. *Semin Nephrol*. 2010 July; 30(4): 366–373 (discussing the three known types of autosomal-dominant interstitial kidney disease). Accordingly, it is axiomatic that family history of these disorders is relevant to the issue of specific causation. Plaintiffs' protestations to the contrary are wholly unsupported.

Additionally, in product liability litigation involving pharmaceutical products, it is commonplace to include a "family medical history" section in the PFS. *See, e.g.*, *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, No. 3:09-md-02100-DRH-PMF, 2010 WL 4386494, at *1 n. 2 (S.D. Ill. Oct. 29, 2010) (noting that certain plaintiffs had failed to "provide responsive and substantially complete answers to questions regarding personal and family medical history" in the Plaintiff Fact Sheet); *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, No. 2:14-mn-02502-RMG, 2016 WL 7376589, at *3 (D.S.C. May 12, 2016) (commenting that the family medical history section, among other

sections in the Plaintiff Fact Sheet, had been entirely left blank by plaintiffs). That is because, in many instances, like here, the plaintiff's genetic make-up and family medical history directly inform issues of causation.

C. Discovery of Social Media Information is Routine and Defendants' Social Media Inquiries Are Tailored to the Issues in this Litigation

Defendants' proposed PFS seeks information (via four discrete questions) regarding the plaintiff's social media presence and activity, specifically such activity as it relates to PPIs and the plaintiff's health. Plaintiffs deleted this section in its entirety without explanation. Numerous courts have weighed the privacy and burden concerns associated with discovery into social media. *See, e.g.*, *Appler v. Mead Johnson & Co., LLC*, No. 3:14-CV-166-RLY-WGH, 2015 WL 5615038, at *2-4 (S.D. Ind. Sept. 24, 2015) (allowing discovery of Plaintiff's complete Facebook Profile); *In the Matter of White Tail Oilfield Services, LLC*, 2012 WL 4857777 (E.D. La. Oct. 11, 2012) (granting a motion to compel discovery request for Facebook information from a plaintiff); *E.E.O.C. v. Simply Storage Mgm't, LLC*, 270 F.R.D 430 (S.D. Ind. 2010) (permitting discovery of social media communications); *Beye v. Horizon Blue Cross Blue Shield*, No. 06-5337 (FSH), 2007 WL 7393489, at *2 (D.N.J. Dec. 14, 2007) (discovery of plaintiff's social media accounts authorized; no reasonable expectation of privacy in information shared with others). Indeed, examining recent decisions on discoverability of plaintiffs' social media, the Court in *Appler* found that "courts have decided that even 'material posted on a 'private' Facebook page . . . is generally not privileged, nor is it protected by common law or civil law notions of privacy.'" *Id.* at *5, quoting *Tompkins v. Detroit Metro. Airport*, 278 F.R.D. 387, 388 (E.D. Mich. 2012). The *Appler* Court likened social media posts to "personal diaries" which "are discoverable if they contain relevant information regarding contemporaneous mental states and impressions of parties." *Id.*

Plaintiffs have articulated no reasonable basis for striking this line of inquiry, and the applicable case law makes it clear that a plaintiff's social media is discoverable. Further, Defendants' social media inquiries are narrowly-tailored to the products at issue here and the plaintiff's physical condition. Those inquiries are proper.

D. The Use of Blank Authorizations to Collect Medical Records is Efficient and Reasonable

The parties also dispute the procedure by which Plaintiffs will provide authorizations for the release of records ("authorizations") to Defendants. Defendants' proposed PFS requires each plaintiff initially to provide the named defendants in his or her

case with 20 blank executed authorizations along with the completed PFS (to be supplemented as needed). Plaintiffs rejected this and propose instead a procedure in which a defendant would have to ask counsel for each plaintiff for fully-addressed and completed authorizations each and every time that defendant wishes to obtain records from a provider. Plaintiffs' proposal would create significant undue delay and expense – only to reach the same point as Defendants' proposal.

Defendants' proposal is efficient and does not prejudice or burden Plaintiffs. Rather, Plaintiffs execute authorizations at the same time as they complete their PFS – in one step. Plaintiffs here have shown difficulty naming the correct PPI manufacturer defendants and are requesting months just to *complete* the PFS. Providing blank authorizations at the same time the plaintiffs complete the PFS is less of a burden on individual plaintiffs, who otherwise will be asked multiple times to complete and execute authorizations. Further, executing blank authorizations at the outset will facilitate the discovery process as additional medical providers are identified. In other words, the additional time, money, and effort of securing piecemeal authorizations largely would be avoided.[5]

Defendants' proposal is not novel and, in fact, has been employed in numerous MDLs across the country. Some courts have simply required plaintiffs to deliver executed blank authorizations to defendants. (*See In re Phenylpropanolamine (PPA) Prod. Liab. Litig.*, 460 F.3d 1217, 1224 (9th Cir. 2006); Proc. Regard. Disc., *In re: Darvocet, Darvon and Propxyphene Prod. Liab. Litig.*, 11-md-2226, at 6-7 (E.D. Ky. May 25, 2012); Pre-Trial Order No. 6, *In re: Bextra and Celebrex Sales Prac. & Prod. Liab. Litig.*, 5-cv-1699, at 3 (N.D. Cal. Feb. 13, 2006).) Other courts have required plaintiffs to provide fully completed authorizations for the medical providers listed in their PFS, as well as an additional number of blank authorizations. (*See In re: Fosamax Prod. Liab. Litig.*, 08-cv-00008, at 27 (D.N.J. Sept. 22, 2011); CMO No. 5, *In re: Gadolinium Based Contrast Agents Prod. Liab. Litig.*, 08-gd-50000, at 3-5 (N.D. Ohio June 16, 2008).) As evidenced by its consistent and effective usage in other courts in similar pharmaceutical product liability MDLs, Defendants' proposal is a practical and well-tested approach to efficiently and cost-effectively collect plaintiff records.

[5] Alternatively, if Plaintiffs' proposal is adopted, the following procedure will occur beyond whatever authorizations are provided with the PFS: (1) the defendant's counsel interested in obtaining certain medical records must contact the plaintiff's counsel to request execution of an authorization for the particular medical provider; (2) the plaintiff's counsel must contact plaintiff; (3) the plaintiff must complete and execute the authorization; (4) the plaintiff must return the authorization to his or her counsel; and (5) the plaintiff's counsel must then deliver the authorization to the requesting defendant's counsel. This procedure would then be repeated numerous times for each and every plaintiff, which inevitably would be wholly inefficient and result in unnecessary expense and discovery delays, and would place an undue burden on Defendants and Plaintiffs alike.

III. Conclusion

For the reasons set forth above, Defendants respectfully request entry of the Plaintiff Fact Sheet in the form proposed by Defendants.

Respectfully submitted,

/s/ Gregory J. Hindy

Gregory J. Hindy

cc: All Counsel of Record (via ECF)